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510(K) SUMMARY

D-STORM Diode Laser System

510(k) Number K 093048

Applicant's Name: Light instruments Ltd
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MAR 2 3 2010

Contact Person: Yoram Levy, Qsite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***D-STORM Diode Laser*** System

Classification:
Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Regulation No: 21 CFR 878.4810
Class: II
Panel: General & Plastic Surgery

Device Description:

The D-STORM Diode Laser is an advanced microprocessor-controlled laser system, composed of the following units:

- Control panel;
- Diode laser
- Safe System Control
- Cooling System
- A hand-piece and foot panel;

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Intended Use Statement:

The ***D-Storm*** system is intended to aid during dental procedures performed in oral and maxillofacial surgery and dentistry.
The ***D-Storm*** diode laser system is indicated for

- Incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry.
- Light activation of bleaching materials for teeth whitening.

The ***D-Storm*** specific indications include the following:
Marginal and interdental gingiva and epithelial lining of free gingiva, frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gigngivioplasty, gingival troughing crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery, debridement of diseased epithelial lining, incision and draining of abscesses, tissue retraction, for impressions, papillectomy, vestibuloplasty, excision of lesions, exposure of unerupted/partially erupted teeth, removal of hyperplastic tissues, treatment of aphtous ulcers, leukoplakia, sulcular debridement (removal of diseased or inflamed soft tissue, in the periodontal pocket), pulpotomy as adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	Manufacture	510k No	Clearance Date
LITEDUO	Light Instruments Ltd	K073411	May 13, 2008
DioDent Micro	Hoya Conbio, Inc	K063384	March 16, 2007
FOTONA XD	FOTONA	K083034	Feb 04, 2009

Performance Standards

D-STORM Diode Laser System complies with U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products. In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the following voluntary standards:

- ***EN 60601-1*** (Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems).
- ***EN 60825-1*** (Safety of laser products);

- ***EN 60601-2-22*** (Medical device equipment, Particular Requirements for the safety and diagnostics and therapeutic laser equipment).
- ***IEC 60601-1-2*** (Electromagnetic compatibility (EMC)

A detailed description appears in **Section 14**.

Summary of Clinical performance data

The safety and efficacy of Diode Laser devices with wavelength of 0.81, 0.98 micron and power up to 7 Watts are well established in scientific research and literature including procedures performed in soft oral tissue, Cosmetic Endodontology and Periodontology.

Due to the comprehensive clinical study performed in scientific research and published in literature, and since the power, wavelength, pulse duration and frequency of the ***D-STORM Diode Laser*** System are well within the previous cleared values, Light Instruments believes that clinical studies are not required to determine the safety and efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAR 2 3 2010

Light Instruments, Ltd.
% Qsite
Mr. Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

Re: K093048
Trade/Device Name: D-STORM Diode Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic Surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 25, 2010
Received: January 29, 2010

Dear Mr. Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093048

Device Name: *D-Storm Diode Laser System*

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Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) for mkm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

(Division Sign-off)